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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,300	03/04/2002	Patricia Rockwell	11245/46211	1694

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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/25/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,300

Applicant(s)

ROCKWELL ET AL.

Examiner

David J Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented the instant claims in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct targets and antagonists to such an extent that they are considered separately patentable. A reference against one would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespectively of the improper format of the claims, because these are not proper species.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-9, 16-21, 28, 62, 63, 65 and 67 in part and claims 10-14 and 22-26 drawn to a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor (VEGFR) and an antibody that binds to the epidermal growth factor receptor (EGFR), classified in class 424, subclass 143.1.
 - II. Claims 1-9, 16-21, 28, 62, 63, 66, and 67 in part and claims 15 and 22-26 drawn to a method of inhibiting tumor growth with an small molecule that binds to the VEGFR and an antibody that binds to the EGFR, classified in class 514, subclass 44.

- III. Claims 1-9, 16-21, 28, 62, 64, 65, and 67 in part and claims 10-14 and 27 drawn to a method of inhibiting tumor growth with an antibody that binds to the VEGFR and a small molecule that binds to the EGFR, classified in class 424, subclass 133.1.
- IV. Claims 1-9, 16-21, 28, 62, 64, 66, and 67 in part and claims 15 and 27 drawn to a method of inhibiting tumor growth with a small molecule that binds to the VEGFR and a small molecule that binds to the EGFR, classified in class 514, subclass 53.
- V. Claims 29-37 and 44 in part and claims 38-42 drawn to a method of inhibiting tumor growth with an antibody that binds to the VEGFR and radiation, classified in class 424, subclass 130.1.
- VI. Claims 29-37 and 44 in part and claim 43 drawn to a method of inhibiting tumor growth with a small molecule that binds to the VEGFR and radiation, classified in class 514, subclass 54.
- VII. Claims 45-53, 60, and 61 in part and claims 45 and 54-58 inhibiting tumor growth with an antibody that binds to the VEGFR and a chemotherapeutic agent, classified in class 424, subclass 138.1.
- VIII. Claims 45-53, 60, and 61 in part and claims 45 and 59 drawn to a method of inhibiting tumor growth with a small molecule that binds to the VEGFR and a chemotherapeutic agent, classified in class 514, subclass 61.

3. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I-VIII differ in the method steps and parameters and in the reagents used. Invention I recites a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor and an antibody that binds to the epidermal growth factor receptor; Invention II recites a method of inhibiting tumor growth with a small molecule that binds to the vascular endothelial growth factor receptor and an antibody that binds to the epidermal growth factor receptor; Invention III recites a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor and a small molecule that binds to the epidermal growth factor receptor; Invention IV recites a method of inhibiting tumor growth with a small molecule that binds to the vascular endothelial growth factor receptor and a small molecule that binds to the epidermal growth factor receptor; Invention V recites a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor and radiation; Invention VI recites a method of inhibiting tumor growth with a small molecule that binds to the vascular endothelial growth factor receptor and radiation; Invention VII recites a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor and a chemotherapeutic agent; Invention VIII recites a method of inhibiting tumor growth with a small molecule that binds to the VEGFR and a chemotherapeutic agent.

The inventions I-VIII are directed to methods that recite different combinations of structurally and functionally distinct elements and are not required one for the other. Invention I recites a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor and an antibody that binds to the epidermal growth factor receptor, which are not required by any of the other inventions. Invention II recites a method of inhibiting tumor growth with a small molecule that binds to the vascular endothelial growth factor receptor and an antibody that binds to the epidermal growth factor receptor, which are not required by any of the other inventions. Invention III recites a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor and a small molecule that binds to the epidermal growth factor receptor, which are not required by any of the other inventions. Invention IV recites a method of inhibiting tumor growth with a small molecule that binds to the vascular endothelial growth factor receptor and a small molecule that binds to the epidermal growth factor receptor, which are not required by any of the other inventions. Invention V recites a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor and radiation, which are not required by any of the other inventions. Invention VI recites a method of inhibiting tumor growth with a small molecule that binds to the vascular endothelial growth factor receptor and radiation, which are not required by any of the other inventions. Invention VII recites a method of inhibiting tumor growth with an antibody that binds to the vascular endothelial growth factor receptor and a chemotherapeutic agent, which are not required by any of the other inventions. Invention VIII recites a method of inhibiting tumor growth with a

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small molecule that binds to the vascular endothelial growth factor receptor and a chemotherapeutic agent, which are not required by any of the other inventions. The examination of all Groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, Inventions I-VIII are separate and distinct in having different method steps and parameters and in the reagents used and are patentably distinct.

4. If Groups II, III, IV, VI or VIII are elected then a species election is required. The species are a) oligosaccharides b) polysaccharides c) polypeptides d) proteins e) amino acids f) oligo and polynucleotides (DNA and RNA) g) nucleosides h) derivatives of biological molecules including lipid and glycosylation derivatives i) organic compounds j) organometallic compounds k) small molecule derivatives and l) small inorganic compounds. The small molecules disclosed for species a - l are patentably distinct because each is structurally and functionally distinct and art on one would not necessarily be art on the others. Claims 1-9, 15-21, 27-37, 43-53, 59-62, 64, 66, and 67 generic to a plurality of disclosed patentably distinct species as indicated above. The examination of all Groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard, whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in


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Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,
David J. Blanchard
703-605-1200



LARRY R. HELMS, PH.D
PRIMARY EXAMINER